

ENZYMATIC THERADY いっコマドウドクマモロ

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NF Formulas & PhytoPharmica Tyler Encapsulations » Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, UK 973. 2 P: 503.582.8386 - F: 503.582.0467 5 PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 & F: 888.570.6460 (Enzymatic) 52 P: 920.469.9099 F: 920.469.4418 (Phyto)
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November 21, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Simple Cleanse* Laxative Formula	The slippery herbs are soothing to the lining of the intestinal tract.*	Magnesium Hydroxide, Proprietary Mucilage Blendslippery elm (Ulmus rubra) bark, marshmallow (Althaea officinalis) root extract, fenugreek (Trigonella foenum-graecum) seed extract, Proprietary Soothing Blend-peppermint (menta x piperita) leaf, fennel (foeniculum vulgare) seed, ginger (Zingabar officinale) rhizome extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/21/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely

Michael P. Devereux

Chief Financial Officer

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INTEGRATIVE THERAPEUTICS INC."

NF Formulas « PhytoPharmica
Tyler Encapsulations « Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 - F: 503.582.0467

ENZYMATIC THERAPY & PHYTOPHARMICA*

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RE: Label Claims/Disclaimers

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Simple Cleanse* Laxative Formula	Soothing herbs support digestion and complement a laxative, making it easier on the intestines.*	Magnesium Hydroxide, Proprietary Mucilage Blendslippery elm (Ulmus rubra) bark, marshmallow (Althaea officinalis) root extract, fenugreek (Trigonella foenum-graecum) seed extract, Proprietary Soothing Blend-peppermint (menta x piperita) leaf, fennel (foeniculum vulgare) seed, ginger (Zingabar officinale) rhizome extract

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By:		

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/21/05

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Simple Cleanse* Laxative Formula	Simple Cleanse Laxative Formula purges the intestine of built-up toxins and promotes healthy, comfortable bowel cleansing and effective detoxification.*	Magnesium Hydroxide, Proprietary Mucilage Blendslippery elm (Ulmus rubra) bark, marshmallow (Althaea officinalis) root extract, fenugreek (Trigonella foenum-graecum) seed extract, Proprietary Soothing Blend-peppermint (menta x piperita) leaf, fennel (foeniculum vulgare) seed, ginger (Zingabar officinale) rhizome extract

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By: Kuldlillit

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/21/05

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Simple Cleanse* Laxative Formula	When the magnesium stays in you colon, it attracts water. As water enters your colon, it naturally loosens and washes the waste substance from your body – no cramping, no rushing to the bathroom, just easier elimination.*	Magnesium Hydroxide

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Simple Cleanse* Laxative Formula	Magnesium Hydroxide is a gentle laxative, which doesn't irritate the intestines, as opposed to stimulant which can lead to pain and discomfort in the bowels.*	Magnesium Hydroxide

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Kaldkill

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/22/05

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